Office Action Summary	Application No.	Applicant(s)	
	10/015,630	CASUSCELLI ET AL.	
	Examiner	Art Unit	
	Jon D Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, drawn to a method for "treating diseases caused by and/or associated with an altered protein kinase activity", classified variously in class 514, subclass 403, 406, 407 depending on the structure of the derivative and its use.

II. Claims 11, drawn to a method for "inhibiting protein kinase" activity, classified variously in class 435, subclass 7.1.

III. Claims 12-20 and 26, drawn to a product described as a "hydroxyaryl-pyrazole derivative" represented by formula (I), classified variously in class 548, subclass 373.1, 377.1 depending on the structure of the compound and its use.

IV. Claims 21 and 27, drawn to a method of making "compounds of formula (I) or the pharmaceutically acceptable salts thereof", classified variously in class 546, subclass 275.4 depending on the structure of the compound and the method steps used to make said compound.

V. Claim 22, drawn to a product described as a "library of two or more compounds of formula (I)", classified variously in 435, subclass 6, DIG 34.

VI. Claim 23-25, drawn to a product described as a "pharmaceutical composition comprising a therapeutically effective amount of a compound of formula (I)" or a "combined preparation for simultaneous separate or sequential use in anticancer therapy, classified variously in class 424, subclass 455, subclass 464+.

2. The inventions are distinct, each from the other because of the following reasons:

3. Groups I-VI represent separate and patentably distinct inventions. Groups I-II, and IV are drawn to different methods and Groups III and V-VI are drawn to different products (i.e., e.g., which are directed to different purposes, use different materials, recite different method or process steps for the preparation of different product(s), screening of different characteristics, such as different binding affinities, different biochemical reaction conditions, etc. or lead to different final results). Therefore, the groups that describe these products and methods have different issues regarding patentability and enablement, and represent patentably distinct subject matter, which merits separate and burdensome searches. Art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features.

4. For example, Groups I-II and IV represent separate and patentably distinct methods. The methods are distinct because they use different steps, require different reagents and/or will produce different results. In the instant case, Group IV requires method steps for "making" compounds of formula (I), which are not required by the method of Groups I-II (e.g., removing Q from a compound of formula (II)). Likewise, Group I requires method steps for "treating diseases", which are not required by the method of Groups II and IV (e.g., administering compound to mammal). Therefore, Groups I-II and VII have different issues regarding patentability and enablement and represent patentably distinct subject matter.

5. Furthermore, Groups III and V-VI represent patentably distinct products. Groups III and V-VII represent separate and patentably distinct products because they differ in respect to their properties, their use and the synthetic methodology for making them. For example, Group VI is drawn to a "pharmaceutical preparation" or a "combined preparation for simultaneous separate or sequential use in anticancer therapy", which requires different reagents and/or materials (e.g., pharmaceutical carrier, diluent, chemotherapeutic agents) than the other groups. Likewise, Group V is drawn to a "library", which requires different reagents and/or materials (e.g., a library) than the other groups. Therefore, art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Different reagents and materials are required to produce a library and a library is also used for a different purpose than a single compound or a pharmaceutical composition (e.g., screening). Consequently, Groups III and V-VI have different issues regarding patentability and enablement and represent patentably distinct subject matter.

6. In addition, if Applicants argue that any of Groups I-III and VI are somehow related as product and process of use, the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product(s) as claimed (i.e., Groups III and VI) can be used in materially different process of using that product

(MPEP § 806.05(h)), for example, the products could be used to (1) treat a disease, (2) inhibit an kinase in an assay system, (3) produce a library for screening, (4) produce a library as starting materials for producing more complex libraries. Furthermore, the treatment of diseases caused by and/or associated with an altered protein kinase activity or inhibition of a protein kinase can be accomplished with materially different compounds (e.g., see specification, page 6, paragraph 1).

7. Finally, if the applicant argues that if any of Groups III, V and VII are somehow related as process of making and product made, the inventions can be considered to be distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different products or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, (2) the product as claimed (e.g., Groups III or VI) can be made by another materially different process e.g., solid-phase synthesis or using starting materials other than Formula (II).

8. Thus, these inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different methods and products would require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

Species Election

9. This application contains claims directed to patentably distinct species of the claimed invention for Groups I-VI. Election is required as follows.

10. If applicant elects the invention of Group I, applicant is required to elect from the following patentably distinct species. Claim 1 is generic.

Subgroup 1: Species of compound shown in formula I (see claim 11)

Applicant must elect for purposes of search a ***single species*** of compound shown in formula I. Furthermore, applicant must show ***all*** atoms and bonds that are necessary to define said compound of general formula I. Applicant should NOT use general notations like R_1, R_2, etc. when defining the structure because these labels represent more than one chemical group and thus more than one compound would be erroneously elected. The Examiner respectfully requests that a "structure" be provided instead of a chemical name.

Subgroup 2: Species of disease (see claim 1)

Applicant must elect, for the purposes of search, a ***single species*** of disease (e.g., Alzheimer's disease (e.g., see claims 1-3). If Applicant elects cancer, Applicant must further pick a species of cancer (e.g., osteosarcoma).

Subgroup 3: Species of mammal (see claim 7)

Applicant must elect, for the purposes of search, a ***single species*** of mammal (e.g., human).

Subgroup 4: Species of cytostatic or cytotoxic agent (see claim 6)

Applicant must elect, for the purposes of search, a ***single species*** of cytostatic or cytotoxic agent if present.

11. If applicant elects the invention of Group II, applicant is required to elect from the following patentably distinct species. Claim 8 is generic.

Subgroup 1: Species of compound shown in formula I (see claim 11)

Applicant must elect for purposes of search a ***single species*** of compound shown in formula I. Furthermore, applicant must show ***all*** atoms and bonds that are necessary to define said compound of general formula I. Applicant should NOT use general notations like R_1, R_2, etc. when defining the structure because these labels represent more than one chemical group and thus more than one compound would be erroneously elected. The Examiner respectfully requests that a "structure" be provided instead of a chemical name.

12. If applicant elects the invention of Group III, applicant is required to elect from the following patentably distinct species. Claim 12 is generic.

Subgroup 1: Species of compound shown in formula I (see claim 12)

Applicant must elect for purposes of search a ***single species*** of compound shown in formula I. Furthermore, applicant must show ***all*** atoms and bonds that are necessary to define said compound of general formula I. Applicant should NOT use general notations like R_1, R_2, etc. when defining the structure because these labels represent more than one chemical group and thus more than one compound would be erroneously elected. The Examiner respectfully requests that a "structure" be provided instead of a chemical name.

13. If applicant elects the invention of Group IV, applicant is required to elect from the following patentably distinct species. Claim 21 is generic.

Subgroup 1: Species of compound shown in formula I (see claim 21)

Applicant must elect for purposes of search a ***single species*** of compound shown in formula I. Furthermore, applicant must show ***all*** atoms and bonds that are necessary to define said compound of general formula I. Applicant should NOT use general notations like R_1, R_2, etc. when defining the structure because these labels represent more than one chemical group and thus more than one compound would be erroneously elected. The Examiner respectfully requests that a "structure" be provided instead of a chemical name.

Subgroup 2: Species of compound shown in formula II (see claim 21)

Applicant must elect for purposes of search a ***single species*** of compound shown in formula II. Furthermore, applicant must show ***all*** atoms and bonds that are necessary to

define said compound of general formula II. Applicant should NOT use general notations like R_1, R_2, etc. when defining the structure because these labels represent more than one chemical group and thus more than one compound would be erroneously elected. The Examiner respectfully requests that a "structure" be provided instead of a chemical name.

14. If applicant elects the invention of Group V, applicant is required to elect from the following patentably distinct species. Claim 22 is generic.

Subgroup 1: Species of library of formula (I) (see claim 22)

Applicant must elect for purposes of search a ***single species*** of compound shown in formula I. Furthermore, applicant must show ***all*** atoms and bonds that are necessary to define said compound of general formula I. Applicant should NOT use general notations like R_1, R_2, etc. when defining the structure because these labels represent more than one chemical group and thus more than one compound would be erroneously elected. The election should result in a ***particularly defined*** core structure that is shared by all library members. In defining this core structure, all variable groups should be defined (i.e. all atoms and bonds shown) as much as possible. The Examiner respectfully requests that a "structure" be provided instead of a chemical name.

15. If applicant elects the invention of Group VI, applicant is required to elect from the following patentably distinct species. Claim 23 is generic.

Subgroup 1: Species of compound shown in formula I (see claim2 23-25)

Applicant must elect for purposes of search a ***single species*** of compound shown in formula I. Furthermore, applicant must show ***all*** atoms and bonds that are necessary to define said compound of general formula I. Applicant should NOT use general notations like R_1, R_2, etc. when defining the structure because these labels represent more than one chemical group and thus more than one compound would be erroneously elected. The Examiner respectfully requests that a "structure" be provided instead of a chemical name.

Subgroup 2: Species of chemotherapeutic agent (see claims 23-25)

Applicant must elect, for the purposes of search, a ***single species*** of chemotherapeutic agent if present (e.g., exemestane).

Subgroup 3: Species of diluent (see claims 23-25)

Applicant must elect, for the purposes of search, a ***single species*** of diluent if present (e.g., lactose).

Subgroup 4: Species of carrier (see claims 23-25)

Applicant must elect, for the purposes of search, a ***single species*** of carrier if present (e.g., olive oil).

16. **Please Note:** Applicants must disclose which claims read on the elected species (see paragraphs 20 and 21 below).

17. The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

18. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

19. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a a rejection under 35 U.S.C. 103(a) of the other invention.

20. Applicant is advised that a reply to this requirement ***must include an identification of the species that is elected consonant with this requirement***, ***and a listing of all claims readable thereon, including any claims subsequently added***. An argument that a claim is allowable or that all claims are generic is considered ***nonresponsive*** unless accompanied by an election.

21. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, ***applicant must indicate which are readable upon the elected species***. MPEP § 809.02(a).

22. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

23. Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

24. Applicant is also reminded that a 1 – month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

25. Finally, Applicant is reminded that where applicant elects claims directed to a product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction

requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

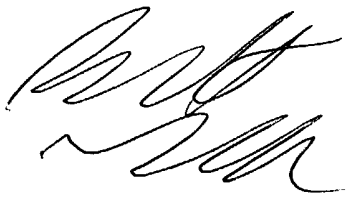
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.
May 27, 2004

BENNETT CELSA
PRIMARY EXAMINER



US 099452540JP1

Creation date: 06-02-2004
Indexing Officer: SSIRIKOOL1 - SOMCHIT SIRIKOOL1
Team: OIPEScanning
Dossier: 09945254

Legal Date: 06-02-2004

No.	Doccode	Number of pages
1	ABN	2

Total number of pages: 2

Remarks:

Order of re-scan issued on .....